# SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY

000406 MAY 135

# THE GENERAL STORE NUMBER TWO, INC., D/B/A MARSH'S SUN FRESH PHARMACY

AND

The General Store Number Two, Inc., D/B/A Marsh's Sun Fresh Pharmacy ("MSF"), through its President, James W. Marsh ("Marsh"), and the Missouri Board of Pharmacy, ("Board"), enter into this Settlement Agreement for the purpose of resolving the question of whether MSF's license as a pharmacy, no. 6016, will be subject to discipline. Pursuant to § 536.060, RSMo 2000, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo Cum. Supp. 2007. The Board and MSF jointly stipulate and agree that a final disposition of this matter may be effectuated as described below pursuant to § 621.045, RSMo Cum. Supp. 2007.

Marsh acknowledges that he understands the various rights and privileges afforded MSF by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses

<sup>&</sup>lt;sup>1</sup> All statutory citations are to the 2000 Revised Statutes of Missouri unless otherwise noted.

appearing against it at the hearing; the right to present evidence on its behalf at the hearing; the right to a decision upon the record of the hearing by a fair and impartial administrative hearing commissioner concerning the charges pending against it; the right to a ruling on questions of law by the Administrative Hearing Commission; the right to a disciplinary hearing before the Board at which time MSF may present evidence in mitigation of discipline; the right to a claim for attorney fees and expenses; and the right to obtain judicial review of the decisions of the Administrative Hearing Commission and the Board.

Being aware of these rights provided to him by law, Marsh knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to MSF.

Marsh acknowledges that he has received a copy of documents that were the basis upon which the Board determined there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. Marsh stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that MSF's license as a pharmacist, license no. 6016, is subject to disciplinary action by the Board in accordance with the relevant provisions of Chapter 621, RSMo Cum. Supp. 2007, and Chapter 338, RSMo, as amended.

The parties stipulate and agree that the disciplinary order agreed to by the Board and MSF in Part II herein is based only on the agreement set out in Part I herein. Marsh understands that the Board may take further disciplinary action against MSF based on facts or conduct not specifically mentioned in this document that are either now known to the Board or may be discovered.

## I. Joint Stipulation of Facts and Conclusions of Law

Based upon the foregoing, the Board and Marsh herein jointly stipulate to the following:

#### Joint Stipulations of Fact

- 1. The General Store Number Two, Inc., d/b/a Marsh's Sun Fresh, holds a license No. 6016 as a Pharmacy issued by the Board. This license was originally issued July 22, 1996, expires October 31, 2009, and is currently active.
  - 2. The owner of MSF is James Marsh ("Marsh").
- 3. Dale Stalder ("Stalder") is a licensed pharmacist, and in December 2006 was the pharmacist in charge of the pharmacy at MSF, at 4001 Mill Street, Kansas City, Missouri 64111.
- 4. On December 9, 2006, Marsh received an unsolicited fax from Secure

  Telemedicine Pharmacy Network (STM). The fax invited independent pharmacies to join
  a network in which STM would send patient's prescriptions to the pharmacy, which

would fill the prescriptions and be reimbursed by STM on a per-prescription basis plus percentage above the cost of the medication filled.

- 5. Marsh presented the fax to Stalder, who expressed the view that it could not be a good idea.
- 6. Nonetheless, at Marsh's suggestion, Stalder made contact with Mario Wilthew, a representative of STM.
  - 7. Wilthew emailed Stalder an explanation of the system and a contract.
- 8. Stalder also received a drug list from STM, and checked it to determine if the prices were reasonable.
  - 9. Stalder signed a contract with STM on February 23, 2007.
  - 10. Marsh knew of and approved the signing of the contract by Stalder.
- 11. Between March 1, 2007, and April 8, 2007, Stalder, his relief pharmacist Khanh Nguyen, and MSF filled 107 prescriptions referred through the STM system.
  - 12. All of the prescriptions were written for Missouri residents.
- 13. All of the prescriptions were electronically prescribed and held only electronic signatures.
- 14. Stalder did not contact the prescribing physicians in each case and confirm the signatures or the validity of the prescriptions.
  - 15. 102 of the 107 prescriptions were for controlled substances.

- 16. Of those 107 prescriptions, 102 were written by Dr. Brian W. Weaver, who was licensed in Missouri, but whose office was located in Atlanta, Georgia.
- 17. Three prescriptions were written by Tansyla Keels-Nicholson, M.D., whose office address was in Henderson, Colorado. Dr. Keels-Nicholson is not licensed in Missouri.
- 18. Two prescriptions were written by Louis M. Fernandez, M.D, whose office address was in Chicago, Illinois. Dr. Fernandez is not licensed in Missouri.
- 19. Stalder spoke on multiple occasions to Drs. Weaver and Keels-Nicholson, but did not confirm that they had a bona fide physician-patient relationship with the patients for whom they were prescribing controlled medications.
- 20. Stalder knew that the physicians were not personally seeing the patients for whom they issued prescriptions through STM and were not performing physical examinations of the patients. Stalder knew that the physicians were writing prescriptions based on telephonic or computer-based consultations or questionnaires.
- 21. After filling prescriptions for almost one month and noticing that almost all the prescriptions were for controlled substances, Stalder contacted the Board of Pharmacy for advice.
- 22. After meeting with Investigator Frank Van Fleet and discussing the arrangement, Stalder notified STM on April 9, 2009, that he was canceling the arrangements and would not fill any more prescriptions.

#### Joint Conclusions of Law

#### 1. Section 338.285, RSMo, provides,

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

#### 2. Section 338.055.2, RSMo, provides in part:

The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
- (13) Violation of any professional trust or confidence; [and]
- (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government . . .

#### 3. Section 195.060, RSMo, provides in part:

1. Except as provided in subsection 3 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. . . .

5. Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

#### 4. 20 CSR Section 2220-2.020(11) provides, in part:

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Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

#### 5. 20 CSR Section 2220-2.090 provides, in part:

The responsibilities of a pharmacist-in-charge, at a minimum, will include: . . .

- (E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws:
- (F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;
- (N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;
- (W) Assure full compliance with all state and federal drug laws and rules;
- (Y) Assure that all state and federal laws concerning drug distribution and control are complied with . . .

#### 6. 20 CSR Section 2220-2.110 provides, in part:

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the prescriber's care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

7. 21 C.F.R. Section 1306.04(a) provides, in part:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

8. 21 C.F.R. Section 1306.05(a) provides, in part:

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued . . . A practitioner may sign a prescription in the same manner as he would sign a check or legal document.

9. MSF is subject to discipline under the terms of Section 338.285 and Section 338.055.2(5), (6), (13), and (15), for having filled prescriptions for controlled substances which had been issued in violation of Section 195.0601. and .5, RSMo, 20 CSR Section 2220-2.020(11), 20 CSR Section 2220-2.110, 21 C.F.R. Section 1306.04(a), and 21 C.F.R. Section 1306.05(a).

## II. Joint Agreed Disciplinary Order

Based on the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §§ 536.060, 621.045.3, and 621.110, RSMo.

1. MSF's license is on probation. MSF's license as a Pharmacy is hereby placed on PROBATION for a period of FIVE (5) YEARS. The period of probation shall constitute the "disciplinary period." During the disciplinary period, MSF shall be entitled to operate as a Pharmacy under Chapter 338, RSMo, as amended, provided MSF adheres to all the terms of this agreement.

#### Terms and conditions of the disciplinary period.

- A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
- B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
- C. Respondent shall keep the Board apprised of all licensed pharmacists employed by the Respondent, and the individuals' current home and work addresses and telephone numbers.
- D. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
- E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every 6 months, beginning 6 months after this Order/Agreement

becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

- F. Respondent shall not serve as an intern training facility for interns.
- G. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.
- H. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.
- 2. Upon the expiration of the disciplinary period, the license of MSF shall be fully restored if all requirements of law have been satisfied; provided, however, that in the event the Board determines that MSF has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline MSF's license.
- 3. No additional discipline shall be imposed by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and opportunity for hearing before the Board as a contested case in accordance with the provisions of Chapter 536, RSMo.

- 4. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning any future violations by MSF of Chapter 338, RSMo, as amended, or the regulations promulgated thereunder, or of the terms and conditions of this Settlement Agreement.
- 5. This Settlement Agreement does not bind the Board or restrict the remedies available to it concerning facts or conduct not specifically mentioned in this Settlement Agreement that are either now known to the Board or may be discovered.
- 6. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the parties agree that the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held, to determine whether a violation occurred and, if so, may impose further disciplinary action. MSF agrees and stipulates that the Board has continuing jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.
- 7. Each party agrees to pay all their own fees and expenses incurred as a result of this case, its litigation, and/or its settlement.
- 8. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

- 9. The parties to this Settlement Agreement understand that the Board will maintain this Settlement Agreement as an open record of the Board as required by Chapters 324, 338, and 610, RSMo, as amended.
- 10. MSF, together with its partners, shareholders, officers, directors, heirs, assigns, agents, employees, representatives and attorneys, does hereby waive, release, acquit and forever discharge the Board, its respective members, employees, agents and attorneys including former members, employees, agents and attorneys, of, or from any liability, claim, actions, causes of action, fees, costs, expenses and compensation, including, but not limited to, any claim for attorney's fees and expenses, whether or not now known or contemplated, including, but not limited to, any claims pursuant to § 536.087, RSMo (as amended), or any claim arising under 42 U.S.C. § 1983, which now or in the future may be based upon, arise out of, or relate to any of the matters raised in this case or its litigation or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of the Settlement Agreement in that it survives in perpetuity even in the event that any court or administrative tribunal deems this agreement or any portion thereof void or unenforceable.
- 11. MSF understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the

parties constitute grounds for disciplining MSF's license. If MSF desires the Administrative Hearing Commission to review this Settlement Agreement, MSF may submit his request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

If MSF requests review, this Settlement Agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the Settlement Agreement sets forth cause for disciplining MSF's license. If MSF does not request review by the Administrative Hearing Commission, the Settlement Agreement goes into effect 15 days after the document is signed by the Executive Director of the Board.

The General Store Number Two,	Inc.,
d/h/a Marsh's Sun Fresh	

James W. Marsh, President

Date: 5-6-09

Missouri Board of Pharmac

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